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K010513
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Appendix 3
510(k) Summary of Safety and Efficacy

1. Sponsor Name

Manufacturer:

Cardiac MRI, a subsidiary of Magna Lab, Inc.
6800 Jericho Turnpike
Suite 120W
Syosset, New York 11791

Primary Contact/Applicant:

MedSource Technologies, Newton Inc
150 California Street
Newton, Massachusetts 02458
Telephone: (617) 964-9100 Fax: (617) 964-2660

Secondary Contact:

Jonathan S. Kahan
Hogan & Hartson L.L.P.
555 Thirteenth Street, N.W.
Washington, DC 20004-1109
Telephone: (202) 637-5794 Fax: (202) 637-5910

2. Device Name

Proprietary Name: Cardiac View 2001
Common/Classification Name: Accessory to Magnetic Resonance Device, 21CFR 892.1000

3. Identification of Predicate or Legally Marketed Device

Legally Marketed Predicate Devices:

The Cardiac MRI, Cardiac View 2001 Transesophageal Probe is determined to be substantially equivalent to the following devices: Surgi-Vision Esophageal Stylet Coil (K994436), Medrad MRInnervu Endorectal Prostate Coil (K926571) and Advanced Technology Laboratories, Inc. Transesophageal Ultrasound Probe (K994373).

4. Device Description

The Cardiac View 2001 Transesophageal MRI Probe is a **receive only coil** intended for placement within the esophagus to obtain high-resolution internal imaging of the area surrounding the esophagus, including the aortic arch, the descending aorta and the

coronary vessels of the heart. The Cardiac View 2001 Transesophageal MRI Probe is comprised of a flexible tube through which a non-magnetic stylet is placed to aid in insertion of the product into the correct position within the esophagus. The flexible tube is approximately 51 cm in length and 8 mm in diameter. Attached to the flexible tube is a balloon that is nominally 10 cm in length and 1.8 cm in diameter. At the proximal end of the device are the connectors that connect the coil within the balloon to the interface circuit and ultimately the MRI system. Also at the proximal end is a standard luer connector through which the stylet is inserted and that is used with an inflation device or syringe for inflation of the balloon.

The balloon, when inflated, serves to stabilize the position of the coil within the esophagus. Within the balloon is imbedded an antenna that serves to receive the electromagnetic waves from the MRI system that are transmitted back to the MRI's system computer for analysis.

5. Indications For Use

The Cardiac View 2001 Transesophageal Probe is indicated for high resolution Magnetic Resonance Imaging. The single use, disposable probe is designed to be inserted into the esophagus of the patient during MRI scans. The Cardiac View 2001 will make images of the area surrounding the esophagus, including the aortic arch, the descending aorta and the coronary vessels of the heart. The unique coil imbedded within the balloon facilitates introduction, placement and the stability of the coil within the esophagus. The Cardiac View 2001 Transesophageal Probe is intended to be used with the General Electric 1.5T Signa® CV/I Magnetic Resonance Imaging Systems.

6. Comparison of Technological Characteristics

The Cardiac View 2001 Transesophageal Probe has similar technological characteristics to the predicate device. Both devices have an electronic circuit, a connecting coaxial cable and a probe with a receiving coil. The differences in design do not affect product safety and effectiveness. This is demonstrated by performance data.

7 Performance Testing

The Cardiac View 2001 Transesophageal Probe has been tested for the following characteristics:

- Possibility of excessive RF heating
- Imaging performance
- Biocompatibility
- IEC 60601-1 and IEC 601-2-33

Studies demonstrate that there is no induced heating over time when the Cardiac View 2001 Transesophageal probe is tested using a test protocol that is representative of clinical conditions. Imaging performance data demonstrates that the Cardiac View 2001 Transesophageal Probe is capable of producing uniform, quality images. Biocompatibility and IEC testing demonstrates that the Cardiac View 2001 Transesophageal probe meets all applicable requirements.

8 Conclusions

This pre-market submission has demonstrated substantial equivalence as defined and understood in the Federal Food Drug and Cosmetic Act and various guidance documents issued by the Center for Devices and Radiological Health.

DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

Food and Drug Administration
9200 Corporate Boulevard
Rockville MD 20850

MAY 21 2001

Cardiac MRI
% Ms. Lynn Carter
Sr. Quality Assurance Engineer
Medsource Technologies, Newton Inc.
150 California Street
NEWTON MA 02458

Re: K010513
Cardiac View, Model 2001
Dated: February 20, 2001
Received: February 21, 2001
Regulatory Class: II
21 CFR §892.1000/Procode: 90 MOS

Dear Ms. Carter:

We have reviewed your Section 510(k) notification of intent to market the device referenced above and we have determined the device is substantially equivalent (for the indications for use stated in the enclosure) to legally marketed predicate devices marketed in interstate commerce prior to May 28, 1976, the enactment date of the Medical Device Amendments, or to devices that have been reclassified in accordance with the provisions of the Federal Food, Drug, and Cosmetic Act (Act). You may, therefore, market the device, subject to the general controls provisions of the Act. The general controls provisions of the Act include requirements for annual registration, listing of devices, good manufacturing practice, labeling, and prohibitions against misbranding and adulteration.

If your device is classified (see above) into either class II (Special Controls) or class III (Premarket Approval), it may be subject to such additional controls. Existing major regulations affecting your device can be found in the Code of Federal Regulations, Title 21, Parts 800 to 895. A substantially equivalent determination assumes compliance with the Current Good Manufacturing Practice requirements, as set forth in the Quality System Regulation (QS) for Medical Devices: General regulation (21 CFR Part 820) and that, through periodic QS inspections, the Food and Drug Administration (FDA) will verify such assumptions. Failure to comply with the GMP regulation may result in regulatory action. In addition, FDA may publish further announcements concerning your device in the Federal Register. Please note: this response to your premarket notification submission does not affect any obligation you might have under sections 531 through 542 of the Act for devices under the Electronic Product Radiation Control provisions, or other Federal laws or regulations.

This letter will allow you to begin marketing your device as described in your 510(k) premarket notification. The FDA finding of substantial equivalence of your device to a legally marketed predicate device results in a classification for your device and thus, permits your device to proceed to the market.

If you desire specific advice for your device on our labeling regulation (21 CFR Part 801 and additionally 809.10 for in vitro diagnostic devices), please contact the Office of Compliance at (301) 594-4639. Additionally, for questions on the promotion and advertising of your device, please contact the Office of Compliance at (301) 594-4639. Also, please note the regulation entitled, "Misbranding by reference to premarket notification" (21CFR 807.97). Other general information on your responsibilities under the Act may be obtained from the Division of Small Manufacturers Assistance at its toll-free number (800) 638-2041 or (301) 443-6597 or at its internet address "http://www.fda.gov/cdrh/dsma/dsmamain.html".

Sincerely yours,

Nancy C Brogdon

Nancy C. Brogdon
Director, Division of Reproductive,
Abdominal, and Radiological Devices
Office of Device Evaluation
Center for Devices and Radiological Health

Enclosure (s)

Section I: General Information

B. Indications for Use Statement

Applicant:

MedSource Technologies, Newton Inc
150 California Street
Newton, Massachusetts 02458
Telephone: (617) 964-9100 Fax: (617) 964-2660

Device Name: Cardiac View 2001 Transesophageal Probe

510(k) Number (if known): K010513

Indications for Use:

The Cardiac View 2001 Transesophageal Probe is indicated for high resolution Magnetic Resonance Imaging. The single use, disposable probe is designed to be inserted into the esophagus of the patient during MRI scans. The Cardiac View 2001 will make images of the area surrounding the esophagus, including the aortic arch, the descending aorta and the coronary vessels of the heart. The unique coil imbedded within the balloon facilitates introduction, placement and the stability of the coil within the esophagus. The Cardiac View 2001 Transesophageal Probe is intended to be used with the General Electric 1.5T Signa® CV/I Magnetic Resonance Imaging Systems.

(PLEASE DO NOT WRITE BELOW THIS LINE – CONTINUE ON ANOTHER PAGE IF NEEDED)

Concurrence of CDRH, Office of Device Evaluation (ODE)

Prescription Use X OR Over-the-Counter Use _____
(Per 21 CFR 801.109)

David C. Segman
(Division Sign-Off)
Division of Reproductive, Abdominal, ENT,
and Radiological Devices
510(k) Number K010513